First Named Inventor: Laurence Lee Application No.: 09/917,433

repeating the coating cycle until a selected amount of coating is placed onto the particle.

REMARKS

-5-

This is responsive to an Office Action mailed on January 24, 2002. In the Office Action the Examiner rejected claims 13-19 and 26-30 as being obvious under 35 U.S.C. § 103(a). In this Amendment, claims 13, 26 and 30 are amended. The application currently includes claims 13-19 and 26-30.

The Examiner rejected claims 13-16, 18 and 26-30 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,858,552, hereinafter the Glatt, et al. patent in view of U.S. Patent No. 3,354,863, hereinafter the Reynolds patent. The Examiner alleged:

Referring to claims 13, 26 and 30, Glatt, et al. disclose a fluidized bed apparatus capable of spraying, coating and drying pellets of pharmaceutical material (column 1, lines 27-38 and column 2, lines 15-21). The fluidized bed, disclosed by Glatt, et al., comprises a perforated base through which fluidized gas flows, a channeling chamber such as a cylindrical rising tube, and a spray nozzle (column 2, lines 54-68 and column 3, lines 1-8). In column 3, lines 63-65, the reference teaches that the channeling cylinder may be vertically adjusted to adapt to different process conditions. The reference further teaches that the spray nozzle may also be adjusted vertically to allow for different particle sizes and densities (column 3, lines 52-56 and 66-68 and column 4, lines 1-2). Glatt, et al. discloses that the particles are carries upwards through the bed and are deflected outward and carried to the lower inlet area of the rising tube to allow for particles to increase in size during the process (column 3, lines 31-36 and 50-53). Glatt, et al. teaches that the particles are loaded into the bed and then are fluidized by an upward flowing gas (column 3. lines 26-36). In FIG. 1, Glatt, et al. discloses that the spray nozzle is adjusted to form a coating region inside of the cylindrical chamber. Furthermore, Glatt, et al. teaches that the circulating fluid allows for drying of the particles during the coating and agglomeration process (column 3, lines 15-21). The particles are circulated through the fluidized bed several times until the particles have reached the appropriate size (column 3, lines 50-55). Glatt, et al. discloses that the multi-medium nozzle which comprises liquid and gaseous components where the gaseous components atomize the liquid, is First Named Inventor: Laurence Lee Application No.: 09/917,433

-6-

used as a spraying means for the coating liquid (column 6, lines 24-35). The reference further teaches that the spraying liquid may be heated to prevent the liquid from solidifying (column 6, lines 33-35). Glatt, et al. do not teach positioning the spray nozzle in a non-heat conducting relationship to the bottom screen. Reynolds teaches a method of coating particles with a liquid and drying the coating (column 1, lines 10-13). The coating apparatus, taught by Reynolds, comprises a cylindrical chamber in the fluidized bed, through which the coating fluid is sprayed, the spray nozzle, which has a coating fluid and an atomizing fluid, and a perforated base through which the fluidizing gas flows (Figure 1 and column 1, lines 27-54). Reynolds discloses that the particles circulate through the apparatus by flowing upward through the cylindrical coating section and flowing downward in the drying section, outside of the cylindrical chamber (column 1, lines 55-42 and column 2, lines 1-5). Reynolds discloses that the spray nozzle comprises a coating material and an atomizing fluid that may be positioned above the perforated plate in a non-heat conducting or it may be positioned flush with the perforated plate. (Figure 1 and column 5, lines 20-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to position the spray nozzle in the fluidized bed coating/agglomeration apparatus, taught by Glatt, et al., above the perforated plate in view of the teachings of Reynolds that placing the nozzle flush with the plate is equivalent to placing it above the perforated plate in a nonheat conducting relation to the perforated plate.

Applicant respectfully disagrees with the Examiner that claim 13 (Twice Amended), is unpatentable under 35 U.S.C. § 103(a) as being obvious over the Glatt, et al. patent in view of the Reynolds patent. Claim 13 (Twice Amended) defines the process as requiring a spray nozzle with a heated liquid line. To provide a liquid at a selected temperature via the heated liquid line after which the liquid is atomized through the spray nozzle. Neither the Glatt, et al. patent nor the Reynolds patent disclose the use of a heated liquid line to maintain the heat of the liquid at a selected temperature.

In contrast to claim 13 (Twice Amended), both the Reynolds patent and the Glatt, et al. patent each disclose heating the liquid by heating the atomizing nozzle. The Reynolds patent discloses as follows:

The bi-fluid nozzle was then heated by passing steam therethrough for a period of about five minutes. The steam was introduced at a First Named Inventor: Laurence Lee Application No.: 09/917,433

-7-

pressure from about 70 to about 100 pounds per square inch gauge and a temperature of about 200-250 degrees centigrade. After preheating the nozzle with steam, an aqueous calcium chloride liquor containing from about 68 to about 70 percent calcium chloride and at a temperature from about 158 to about 162 degrees centigrade was introduced to the column through the bi-fluid nozzle at a rate of about 200 to 250 pounds per hour of calcium chloride while steam was also introduced through the bi-fluid nozzle as before.

(Column 4, lines 20-33). Therefore the Reynolds patent does not disclose providing a spraying liquid at a selected temperature by a heated liquid line.

Similarly, the Glatt, et al. patent does not disclose the use of a heated liquid line to maintain a temperature of a liquid to be sprayed at a selected temperature. The Examiner alleged "the reference further teaches that the spraying liquid may be heated by preventing the liquid from solidifying (column 6, line 33-35)." The Glatt, et al. patent does not disclose that the spraying liquid may be heated by the liquid line to prevent the liquid from solidifying, rather, the Glatt, et al. patent discloses:

The spraying means 6 can also be heated to prevent the spray media from solidifying.

(Column 6, lines 33-35). Referring to FIG. 1, the spraying means, as called out by reference numeral 6, is the spray nozzle into which the liquid and the atomizing gas are combined. The Glatt, et al. patent does not disclose providing a liquid at a selected temperature via a heated liquid line.

The Glatt, et al. patent in view of the Reynolds patent, does not disclose each and every element of claim 13 (Twice Amended). Therefore the Glatt, et al. patent in view of the Reynolds patent does make claim 13 (Twice Amended) unpatentable under 35 U.S.C. § 103(a) as being obvious. Reconsideration and allowance of claim 13 (Twice Amended) are respectfully requested.

Claims 14 -19 depend from claim 13 (Twice Amended). Because claims 14-19 depend from a claim which is believed to be allowable, claims 14-19 are also in allowable form. Reconsideration and allowance of claims 14-19 are respectfully requested.

First Named Inventor: Laurence Lee Application No.: 09/917.433

-8-

The Examiner also rejected claim 26 as being obvious in view of Glatt, et al. patent in view of the Reynolds patent. Claim 26 (Amended) includes the elements of providing a heated liquid to a spray nozzle maintained at a selected temperature with a heated liquid line such that the liquid is sprayed within the cylindrical insert at a selected temperature and providing the atomized liquid at a selected temperature through the spray nozzle.

As previously mentioned in the discussion of claim 13 (Twice Amended), neither the Glatt, et al. patent nor the Reynolds patent disclose the use of a heated liquid line to maintain the temperature of a liquid to be sprayed upon particles. Therefore, for the same reasons relating to claim 13 (Twice Amended), claim 26 (Amended) is believed to be in allowable form. Reconsideration and allowance of claim 26 (Amended) are respectfully requested.

Because independent claim 26 (Amended) is in allowable form, claims 27-29 which depend from independent claim 26 (Amended) are also believed to be in allowable form. Reconsideration and allowance of claims 27-29 are respectfully requested.

The Examiner also rejected claim 30 as being unpatentable under 35 U.S.C. § 103(a) over the Glatt, et al. patent in view of the Reynolds patent. Claim 30 (Amended) also includes elements of supplying a coating solution to the spray nozzle at a selected temperature via the heated line. For the same reasons claims 13 (Twice Amended) and 26 (Amended) are allowable. Claim 30 as amended is also allowable. Neither the Glatt patent nor the Reynolds patent teach or suggest heating the liquid through a heated line. Therefore, the Glatt, et al. patent in view of the Reynolds patent does not make claim 30 (Amended) obvious. Reconsideration and allowance of claim 30 (Amended) are respectfully requested.

In response to the Examiner's objection to the Information Disclosure Statement's failure to comply with the 37 C.F.R. § 1.98(a)(2). Applicant is enclosing herewith a duplicate Information Disclosure Statement with copies of each document listed.

For the foregoing reasons, Applicant respectfully requests reconsideration and allowance of claims 13 (Twice Amended), 14-19, 26 (Amended), 27-29, and 30 (Amended).

The Commissioner is authorized to charge any additional fees associated with this

First Named Inventor: Laurence Lee

-9-

Application No.: 09/917,433

paper or credit any overpayment to Deposit Account No. 11-0982. A duplicate copy of this communication is enclosed

> Respectfully submitted, KINNEY & LANGE, P.A.

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APPENDIX: MARKED UP VERSION OF SPECIFICATION AND CLAIM AMENDMENTS

13. (Twice Amended) A process for coating particles comprising:

providing an insert within an upward flowing fluid bed dryer or granulator with a screen across the bottom of the dryer or granulator, the insert comprising a vertically adjustable cylindrical partition located substantially on a vertical axis of the granulator or dryer, a spray nozzle with a heated liquid line and an atomizing gas line connected thereto which is positioned such that a liquid is sprayed within the adjustable cylindrical partition at a selected temperature, the spray nozzle being positioned in a non-heat conducting relation to the bottom screen, the spray nozzle being located substantially on the vertical axis;

Application No.: 09/917,433

loading the dryer with a bed of particles:

adjusting the cylindrical partition such that the position of the top of the cylindrical partition is above the bed of particles and product can be removed from the dryer;

adjusting the spray nozzle such that a spray zone is created within the cylindrical partition;

providing a gas to fluidize the bed of particles through the bottom screen;
providing an atomizing gas which is processed through the spray nozzle;
providing [a] the liquid at the selected temperature through the heated liquid line
which is atomized through the spray nozzle;

contacting the particles with the liquid from the spray nozzle within the cylindrical partition and spray zone;

drying the particles in an area outside the partition; and

circulating the particles from the fluidized bed up through the cylindrical partition, down through the drying zone and back into the

APPENDIX: MARKED UP VERSION OF SPECIFICATION AND CLAIM AMENDMENTS

fluidized bed until a selected amount of liquid is coated onto the particles.

26. (Amended) A process for coating particles comprising:

providing a cylindrical insert whose central axis is disposed in a vertical direction within an upward flowing fluid bed dryer such that fluidized particles within the fluid bed dryer travel upwardly through the insert, and a spray nozzle supplied with a heated liquid sustained at a maintained temperature with a heated liquid line such that [a] the liquid is sprayed within the cylindrical insert, and the spray nozzle being disposed in a non-heat conducting relation with regard to a bottom screen within the fluid bed dryer, the spray nozzle being located substantially along the central axis of the cylindrical insert;

loading the drver with particles to be coated;

adjusting the cylindrical partition's vertical position within the fluid bed dryer: adjusting the spray nozzle such that a spray zone is created within the cylindrical insert;

fluidizing the particles with a gas stream in an upward direction such that particles travel through the cylindrical insert;

providing an atomized liquid <u>at the selected temperature</u> through the spray nozzle to coat the particles within the cylindrical insert:

permitting the particles to dry outside of the cylindrical partition; and recirculating the particles through the cylindrical insert until a selected amount of liquid is coated onto the particles.

30. (Amended) A method for coating particles within a dryer that is capable of fluidizing a bed of particles, the method comprising:

First Named Inventor: Laurence Lee -A3- Application No.: 09/917,433

APPENDIX: MARKED UP VERSION OF SPECIFICATION AND CLAIM AMENDMENTS

positioning a cylindrical partition having an axis extending concentrically therein such that the axis is disposed vertically with respect to upward flow of gas through the cylindrical partition creating a coating zone within the partition and above the partition and a drying zone outside of the coating zone:

positioning a spray nozzle along the axis of the cylindrical partition for spraying a coating solution onto the particles such that the spray from the nozzle coats the particles within the partition and in an area above the partition;

supplying the coating solution to the spray nozzle at a selected temperature via a heated line;

fluidizing the bed of particles such that particles flow through the partition in an upward fashion for coating and travel upwardly and outside of the coating zone and then downwardly settling outside of the partition and coating zone for drying creating a coating cycle: and

repeating the coating cycle until a selected amount of coating is placed onto the particle.